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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,658	10/27/2006	Karlheinz Brunner	460868.00020	1917

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,658	BRUNNER ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-8 and 11-14* is/are rejected.

7)☒ Claim(s) *2,3,5,19 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

1. Claim amendment and arguments filed 12/17/2008 is acknowledged. Claims 1-22 are present.

2. Claims 1-8, 11-14 & 19-22 drawn to a process for the enzymatic synthesis of oil and /or fat with simultaneous enzymatic formation of fatty acid esters are under consideration.

3. **Claims withdrawn**:

Claims 9-10 & 15-18 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant's arguments filed with the amendment filed 12/17/2008 have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

5. Any objection or rejection of record not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

6. Claim 1, line 6, recites the phrase "an alcohol soluble in oil or fat". There is a typographical error which may be corrected by replacing the phrase with "an alcohol soluble ~~in~~ oil or fat". This will give the appropriate meaning of the fat or oil being soluble in alcohol, rather than the other way around. Correction is required.

7. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6-8, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosh et al. [J.Am.Oil Chem.Soc.; (1996) 72, 12, 1541-44] and Buhler [Fat Science Technology, 89(14): 598-605 (1987), cited in PTO-1449].

Claims 1, 4 & 6-8 are drawn to a process for the enzymatic synthesis of oil and /or fat with simultaneous enzymatic formation of fatty acid esters using lipases acting as biocatalysts and alcohols wherein the free fatty esters are separated by distillation or wherein the organic phase is drained out from the self-discharging centrifuge. This means that any other alcohol may also be used, example glycerol. Claims 11-14 are drawn to a process for the enzymatic synthesis of oil and /or fat with simultaneous enzymatic formation of fatty acid esters using lipases acting as biocatalysts and glycerol.

Ghosh et al. teach microbial lipase technology to have enormous potential for making ester derivatives for various specific industrial applications. Microbial lipase (EC-3.1.1.3)-catalyzed hydrolysis, esterification, and alcoholysis reactions were carried out on acid oils. For hydrolysis reactions, the substrate (20 g acid oil) was placed in a 100 ml Erlenmeyer flask. Water (60% weight of acid oil) containing 0.08 g (0.4% weight of acid oil) of *Candida cylindracea* lipase (EC-3.1.1.3) powder was added. The reaction mixture was stirred at 33-37^{o}C. For simultaneous esterification and alcoholysis, acid oils (1.0 g) and different alcohols in 1:1molar ratio were taken in a 10 ml round-bottomed flask and stirred at 58-62 ^{o}C for 4 hr with 10% (weight of acid oil) of *Mucor miehei* lipase. Neutral glycerides of the acid oils were hydrolyzed by *C. cylindracea* lipase almost completely within 48 hr. Acid oils were converted into fatty acid esters of short- and long-chain alcohols like C4, C8, C10, C12, C16, and C18 in high yields by the simultaneous esterification and alcoholysis reactions with *M. miehei* lipase.

The reference does not teach the use of centrifugal phase separation and recovery of the enzyme (used for esterification and alcoholysis) for recycling of the enzymatic process.

Buhler et al. teach enzymatically catalyzed reactions, especially in the pharmaceutical field, the product-added value to be derived from the fat-splitting process is low. On the other hand fatty acids have a remarkable market volume. Continuous processing, with reuse of the enzyme, seems to be the biotechnological method of choice. In order to achieve high space-time-yields, carrier fixation of a lipase may be unfavorable due to mass transfer limitations, especially in the case of two-phase reaction systems. Buhler et al. developed a method for the continuous use of lipases without carrier fixation. Since the enzyme is enriched at the phase boundary (fat/water) where the reaction takes place, a micro-emulsion is desirable, and phase separation is necessary for product isolation and for recovery of the enzyme. This was accomplished by the use of two stirred tank reactors and two continuously operating centrifuges or polishing centrifuges. The conditions were selected so that about 90% of the pure aqueous phase containing glycerol (first stage), and about 90% of the pure fat phase containing fatty acids "(second stage), were separated. By this series of two incomplete separations it was possible to recycle about 90 % of the enzyme together with the inter-facial layer. This procedure allows a kinetically and thermodynamically desirable counter-current flow of the fat and the aqueous phases. *See* Figures 1-13, for the degree of hydrolysis, reaction rate, the process scheme, enzyme recycling, self discharging centrifuges, means of separating fatty acid products, use of glycerol (an alcohol) and the various variations in the process steps.

Buhler et al. do not teach alcoholysis and esterification using a lipase.

It would have been obvious to one of ordinary skill in the art to use the alcoholysis and esterification process employed by Ghosh et al. and combine with centrifugal phase separation and recovery of the enzyme (used for esterification and alcoholysis) for recycling of the enzymatic process for extended use of the lipase enzyme by the method of Buhler et al. in order develop a process for making fatty acid esters or derivatives from fats or oils and do so with a reasonable expectation of

success. It would have been further obvious for one of ordinary skill in the art to vary the temperature and alcohol used for the conversion of oils or fats to fatty acid esters of short- and long-chain alcohols like C4, C8, C10, C12, C16, and C18 by employing what is well know in the art as high lighted by the teachings of Ghosh et al and Buhler et al.

One of ordinary skill in the art would have been motivated to combine the teachings of Ghosh et al and Buhler et al. to make a range of fatty acid esters in view of the known use of various ester derivatives as raw material for chemical industry (Buhler et al., page 598, column 1, Introduction). The recycling of the enzyme helps reduce the high cost of the enzyme used in the process and is suggested in the works of Buhler et al. (*See* page 598, column 2, Introduction).

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, *prima facie* obvious.

8. Claims 2-3, 5 & 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272

0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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